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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,923	04/30/2001	Patrick Kennedy	1022-11	4246

7590

08/26/2003

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 08/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/845,923	KENNEDY, PATRICK	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,10-22,24-28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8,10-19,22,24-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 6/16/03 has been entered.

Claims 1-8, 10-22, 24-28 and 30-32 are pending in the application. Claims 1-3 and 20 were previously withdrawn from further consideration as they are drawn to a non-elected invention (Paper No. 3).

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 were presented for examination on the merits.

Claim Objections

Claim 13 is objected to because of the following informalities:

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Claim 13, line 4 recites ' and effective amount'. This phrase is grammatically incorrect as it is lacking an article; i.e., 'an'.

Appropriate correction is required.

Specification

The use of the trademark BENADRYL and NEOSPORIN have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4-8, 10-22, 24-28 and 30-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-8, 10-22, 24-28 and 30-32 all recite, or depend upon a claim which recites 'to relieve the itch, pain, and swelling associated therewith'. This phrase is considered to lack antecedent basis in the claim, because although the claim previously recited the term 'insect bites and stings', insect bites and stings are not always associated with itch, pain and swelling.

Further, Claims 4-8, 10-22, 24-28 and 30-32 either recite, or depend upon a claim which recites 'the site'. This phrase lacks antecedent basis in each claim which recites this phrase.

Claims 11, 19 and 31 are indefinite for the recitation of the trademarks 'Benadryl' and 'Neosporin'. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. It is asked that the trademarks be removed from the claims in order to overcome this rejection.

Claims 11, 19 and 31 further all recite the term 'such as'. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Applicant is asked

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to remove this language from the claims in order to overcome this rejection. As another suggestion, Applicant may replace the term 'such as' with Markush-type language :
'antimicrobial agents selected from the group consisting of A, B and C'.

Claims 5, 10, 18, 30 and 32 all recite 'The pharmaceutical composition'; however, appear to be new independent claims. The Examiner cannot be certain that these are independent claims. Thus, Applicants are required to clarify the claims in order to more clearly show that they are independent; i.e., 'A pharmaceutical composition...'. It is noted that these claims were examined on the merits as if they were independent claims. The Examiner reasonably concludes that this was the intent of the Applicant, since all of these claims had previously depended upon other claims, but Applicant has amended the claims to delete the dependency language; i.e., 'according to claim 4' has been deleted from claim 5. Appropriate correction is necessary. (Please also note that amending these claims to specifically recite independent claims may be subject to fees).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 99/37287).

Lee (WO 99/37287) disclosed a method for treating inflammatory skin disorders with a bioactive glass (Claim 1). Lee further disclosed the bioactive glass in combination with lotions or with additional therapeutic agents such as anesthetics and anti-inflammatory agents (claim 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO 99/ 37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 above.

The teachings of Lee (WO 99/37287) were discussed *supra*. Lee did not specifically teach wherein the carriers for the bioactive glass was a liquid, an aqueous pharmaceutical carrier, or a paste.

Although Lee did not specifically teach wherein the bioactive glass was formulated into an aqueous carrier, or as a paste, Lee did teach that "The bioactive glass and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin" (p.4, lines 22-25). Therefore, because water and pastes were conventional, inert carriers for pharmaceuticals, the ordinary artisan would have had a reasonable expectation that water or pastes would have been suitable vehicles for topically applying the bioactive glass composition.

Claims 5, 12-19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO 99/ 37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 above, and further in view of Rubin (US 5,543,149).

The teachings of Lee (WO 99/37287) were discussed *supra*.

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Although Lee taught the administration of the composition could have included agents such as benzocaine and lidocaine and topical anesthetics for relief of inflammatory conditions, Lee did not teach wherein an anti-itch enzyme was added into the composition. Lee further did not teach wherein the composition was in the form of a paste or liquid or in an aqueous pharmaceutical carrier.

Rubin (US 5,543,149) taught a method for treating insect bites with digestive enzymes such as papain and pancreatin (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating insect bites/stings. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore obvious.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

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Further, although Lee did not specifically teach wherein the bioactive glass was formulated into an aqueous carrier, or as a paste, Lee did teach that "The bioactive glass and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin" (p.4, lines 22-25). Therefore, because water and pastes were conventional, inert carriers for pharmaceuticals, the ordinary artisan would have had a reasonable expectation that water or pastes would have been suitable vehicles for topically applying the bioactive glass composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

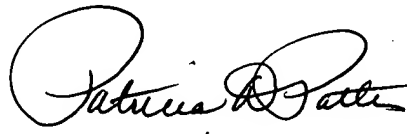
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


8/22/03